

**CRITERIA FOR PRIOR AUTHORIZATION**

Mavyret™ (glecaprevir/pibrentasvir)

**PROVIDER GROUP** Pharmacy**MANUAL GUIDELINES** The following drug requires prior authorization:  
Glecaprevir/Pibrentasvir (Mavyret™)**CRITERIA FOR INITIAL APPROVAL** (must meet all of the following):*\*Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of up to the duration listed below)\**

- Patient must have a diagnosis of chronic hepatitis C virus (HCV)
- Patient must have genotype 1, 2, 3, 4, 5, or 6 hepatitis C
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Patient must be 18 years of age or older
- Patient must not be on a concurrent direct acting hepatitis C agent or ribavirin
- Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months
- Patient has a pre-treatment HCV RNA level drawn and results are submitted with PA request
- Dose must not exceed 3 tablets per day
- Patient must have one of the following:
  - Advanced fibrosis (Metavir F3 or greater)
  - Compensated cirrhosis
  - Organ transplant
  - Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g., vasculitis)
  - Proteinuria
  - Nephrotic syndrome
  - Membranoproliferative glomerulonephritis
- Patient must not have moderate or severe hepatic impairment (Child-Pugh class B or C)
- Patient must not be concurrently prescribed atazanavir or rifampin
- For all genotypes: the PDL preferred drug, which covers that specific genotype, is required unless the patient has a documented clinical rationale for using the non-preferred agent supported by the label or AASLD/IDSA HCV guidelines
- Patient must be tested for evidence of current or prior hepatitis B virus (HBV) infection by measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) before initiating HCV treatment

**CRITERIA FOR RENEWAL** (must meet all of the following):

- Prescriber must document adherence by patient of greater than or equal to 90%
- Must meet one of the following:
  - Genotype 1 (one of the following):
    - Treatment naïve AND without cirrhosis – **8 weeks total duration**
    - Treatment naïve AND with compensated cirrhosis (Child-Pugh A) – **12 weeks total duration**
    - Without cirrhosis AND prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor – **8 weeks total duration**
    - With compensated cirrhosis (Child-Pugh A) AND prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor – **12 weeks total duration**

PA Criteria

- Without cirrhosis or with compensated cirrhosis (Child-Pugh A) AND prior treatment experience with a regimen containing an NS3/4A PI\* without prior treatment with an NS5A inhibitor – **12 weeks total duration**
- Without cirrhosis or with compensated cirrhosis (Child-Pugh A) AND prior treatment experience with a regimen containing an NS5A inhibitor\*\* without prior treatment with an NS3/4A PI – **16 weeks total duration**
- \* simeprevir and sofosbuvir, or simeprevir, boceprevir, or telaprevir with pegylated interferon and ribavirin
- \*\*ledipasvir and sofosbuvir or daclatasvir with pegylated interferon and ribavirin
- Genotype 2, 4, 5, or 6 (one of the following):
  - Treatment naïve AND without cirrhosis – **8 weeks total duration**
  - Treatment naïve AND with compensated cirrhosis (Child-Pugh A) – **12 weeks total duration**
  - Without cirrhosis AND prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor – **8 weeks total duration**
  - With compensated cirrhosis (Child-Pugh A) AND prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor – **12 weeks total duration**
- Genotype 3 (one of the following):
  - Treatment naïve AND without cirrhosis – **8 weeks total duration**
  - Treatment naïve AND with compensated cirrhosis (Child-Pugh A) – **12 weeks total duration**
  - Without cirrhosis or with compensated cirrhosis (Child-Pugh A) AND prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor – **16 weeks total duration**

**LENGTH OF APPROVAL FOR GLECAPREVIR/PIBRENTASVIR: 4 weeks**

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR

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DATE

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PHARMACY PROGRAM MANAGER  
DIVISION OF HEALTH CARE FINANCE  
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

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DATE